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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/599,760	06/22/00	NEWELL M	I0277/7009 H

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EXAMINER	
ZARA, I	
ART UNIT	**PAPER NUMBER**
1635	8

DATE MAILED: 03/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/599,760	Applicant(s) NEWELL, MARTHA K.	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Claims 1-74 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to methods of inhibiting plasma membrane UCP expression in a target cell, classified in class 435, subclasses 455 and 471.

II. Claims 12-28, drawn to plasma membrane targeted UCP inhibitors, classified in classes 424 and 536, subclasses 9.2 and 24.5.

III. Claims 29-31, drawn to methods for preventing or treating a cancer, classified in class 514, subclasses 2 and 44.

IV. Claims 32-34, 36 and 37, drawn to lysosomal targeted UCP inhibitors which are antibodies, classified in class 424, subclass 134.1.

V. Claims 35, 38-47, 51-59, drawn to compositions and methods for screening tumor cells for chemotherapeutic susceptibility, for sensitizing resistant tumor cells for cytotoxic therapy, and for screening subjects for the presence of rapidly dividing cells comprising the detection or administration of nucleic acids encoding plasma membrane UCP, classified in class 435, subclasses 6 and 23.1.

VI. Claims 35, 38-46, 48-51 and 56-59, drawn to compositions and methods for screening tumor cells for chemotherapeutic susceptibility, for sensitizing resistant

tumor cells for cytotoxic therapy, and for screening subjects for the presence of rapidly dividing cells comprising the detection or administration of polypeptides encoding plasma membrane UCP, classified in class 530, subclasses 300 and 350.

VII. Claims 60-64, 66-72, drawn to methods of regulating lysosomal pH and methods of treating or preventing an infectious disease, comprising contacting a cell with a lysosomal UCP inhibitor, classified in class 514, subclass 1.

VIII. Claims 60-62, 65, 73 and 74, drawn to methods of regulating lysosomal pH and methods of treating an autoimmune disease comprising contacting a cell with a lysosomal UCP activator, classified in class 514, subclasses 2 and 44.

Claims 1-12, 18-21, 25-27, 29-32, 36, 37, 52-55, 60-73 are generic to a plurality of disclosed patentably distinct species comprising UCP inhibitors, UCP activators, membrane attachment domains, target cell types and chemotherapeutic agents. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for each of the following, even though this requirement is traversed:

For each Group please pick a species of UCP inhibitor, a target cell, a membrane attachment domain and, where appropriate, a chemotherapeutic agent. Upon election of a single group, the generic claims will be examined according to the Group and the species elected.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim 28 is drawn to nucleotide or amino acid sequences, constructs, and/or methods requiring the use of nucleotide or amino acid sequences or constructs that contain more than one individual, independent, and distinct nucleotide or amino acid sequence in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (Nov. 19, 1996).

Applicant is required to select **no more than one** of the individual sequences for examination. The search of no more than one selected sequence may include the complements of the selected sequence and, where appropriate, may include subsequences within the selected sequence (e.g., oligomeric probes and/or primers).

The inventions are distinct, each from the other because of the following reasons:

The UCP inhibitors of Group II and the antibodies of Group IV are chemically, biologically, structurally and functionally distinct from each other and thus one does not render the other obvious. The inhibitors of Group II are not required to produce the antibodies of Group IV, and the antibodies of Group IV are not required to make the nucleic acids or other inhibitors of Group II. Therefore, the inventions of the two groups are capable of supporting separate patents.

The products of Groups II and IV are biologically and functionally different and distinct from the methods of Groups I, III, and V-VIII and thus one does not render the other obvious. The products of Groups II and IV are not required for the methods of Groups I, III and V-VIII and the operation, function and effects of each of the products of Groups II and IV are completely different and distinct from the operation, function and effects of the methods of Groups I, III and V-VIII, which respectively inhibit UCP expression, screen for chemotherapeutic susceptibility, sensitize resistant tumor cells for cytotoxic therapy, screen for rapidly dividing cells, regulate lysosomal pH, treat and prevent cancer, infectious diseases and autoimmune diseases. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The inventions of Groups I, III and V-VIII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I, III, V, VI, VII and VIII each comprise steps which are not required for or present in the methods of the other groups, and the end results of each of the methods are different: inhibiting plasma membrane UCP expression in a target cell (Group I), preventing or treating cancer (Group III), screening tumor cells for chemotherapeutic susceptibility, sensitizing resistant tumor cells for cytotoxic therapy and screening subjects for the presence of rapidly dividing cells comprising the administration of nucleic acids (Group V), screening tumor cells for chemotherapeutic susceptibility, sensitizing resistant tumor cells for cytotoxic therapy and screening subjects for the presence of rapidly dividing cells comprising the administration of polypeptides (Group VI), regulating lysosomal pH and treating or preventing an infectious

disease (Group VII) and regulating lysosomal pH and treating autoimmune diseases (Group VIII). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

March 22, 2001

ANDREW WANG
PATENT EXAMINER
TC 1600